SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY

COMPANY NAME AND CONTACT PERSON

June 02, 2000

Jostra AG
Hechinger Straße 38
72145 Hirrlingen
Germany

Kathy Johnson, Product Manager
Phone 888-567-8721
fax (302) 454 8700

DEVICE NAME

Quart Arterial Filter HBF 140

COMMON NAME

Cardiopulmonary Arterial Blood Filter

CLASSIFICATION NAME

Cardiopulmonary bypass arterial line blood filter (21 CFR – 870.4260)

PREDICATE DEVICE OR LEGALLY MARKETED DEVICE

Avecor Cardiovascular, Inc. - Affinity Arterial Filter (K 952532)

DEVICE DESCRIPTION

The Arterial Filter Quart HBF 140 is a screen filter with an integrated bypass and a pre/post deaerator mechanism. During extracorporeal circulation, the Arterial Filter Quart removes gaseous embolisms and blood component aggregates from the arterial blood line, thus reducing the risk of gases or solid bodies forming a microembolism in the patient.

INTENDED USE

The arterial filter is designed for use in an extracorporeal circulation system during surgical procedures involving a cardiopulmonary bypass lasting 6 hours or less. Within the cited flowrates, the arterial filter removes particulate and gaseous micro-embolisms from the extracorporeal circulation system.

TECHNOLOGICAL CHARACTERISTICS

Name of the Product	Quart Arterial Filter HBF 140 (Jostra)	Affinity Arterial Filter (Avecor)
Parameter		
510(k) number	not assigned	K952532
Specifications:		
Recommended blood flow rate	up to 7 liters/minute	up to 7 liters/minute
Prime volume	180 ml	212 ml
Screen size	40 micron	38 micron nominal
Filter surface area	~~750~~ cm² 510cm² - Lot	unknown
Blood inlet connector	3/8"	3/8"
Blood outlet connector	3/8"	3/8"
Vent port	Luer Lock	Standard Female Luer Lock
Pressure measurement	Luer Lock	unknown
Method of sterilization	Ethylene Oxide	unknown
Storage temperature	+15°C - +30°C (+59° -+86°F)	unknown
Use	Single-use device	Single-use device

SAFETY TESTING

Biocompatibility and Blood Cell Damage:

Biocompatibility testing of the Quart Arterial Filter was performed in accordance with the FDA Blue Book Memorandum - #G95-1 and Biological Evaluation of Medical Devices Guidance – International Standard ISO 10993-1, and in accordance with United States Pharmacopeia – XXIII.

Based on the results of the biocompatibility testing performed, the Quart Arterial Filter HBF 140 was determined to be biocompatible and nontoxic and, therefore, safe for its intended use.

Blood cell damage testing of the Quart Arterial Filter HBF 140 has been performed by utilizing fresh heparinized bovine blood circulated at specified constant flow rates for a six hour period.

Sterility:

Sterilization of the Quart Arterial Filter HBF 140 has been validated to assure a sterility assurance level (SAL) of 10^{-6}.

EtO sterilized Quart Arterial Filter are according to Federal Register , Vol. 43, No. 122 – Friday, June 23, 1978.

EtO Residuals:

Quart Arterial Filter HBF 140 meets the limits for residual concentrations of ethylene oxide (<25 ppm), ethylene chlorohydrin (<25 ppm), and ethylene glycol (< 250 ppm) as published in Federal Register , Vol. 43, No. 122 – Friday, June 23, 1978.

Pyrogens:

Routine Pyrogen Testing is performed using the Limulus Amebocyte Lysate (LAL) method. Product testing and release criteria (less than 20 EU/ml) is in accordance to the December 1987 Guideline issued by the Food and Drug Administration, office of Compliance („Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices").

EFFECTIVENESS TESTING

Effectiveness of the Quart Arterial Filter was determined by evaluating its operational characteristics as defined by the following tests:

- Priming Volume
- Flow Rate Capacity
- Air Handling Capability
- Filtration Efficiency

Performance by the above testing shows that the Quart Arterial Filter is effective and meets all functional requirements of an Arterial Blood Filter.

Conclusion

Performance, function, sterility and biocompatibility testing demonstrated that Quart Arterial Filter HBF 140, when compared to the Predicate device (Affinity Arterial Filter), does not significantly affect safety and effectiveness and thus is substantially equivalent to the Affinity Arterial Filter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2000

Ms. Kathy Johnson
Product Manager
Jostra Medizintechnik AG
2035 Sunset Lake Road
Newark, DE 19702

Re: K001787
Quart Arterial Filter, Model HBF 140
Regulatory Class: III (three)
Product Code: DTM
Dated: June 2, 2000
Received: June 13, 2000

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K001787

Device Name: Quart Arterial Filter HBF 140

Indications for Use Quart Arterial Filter HBF 140
The arterial filter is designed for use in an extracorporeal circulation system during surgical procedures involving a cardiopulmonary bypass lasting 6 hours or less. Within the cited flowrates, the arterial filter removes particulate and gaseous micro-emboliSms from the extracorporeal circulation system.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N. Melkerson
Steven Gitlin

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001787

(Optional Format 3-10-98)